



+

Approved for use through 10/31/2002. OMB 0851-0031
Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it contains a valid OMB control number.

Complete if Known

Application Number	09/757,688
Filing Date	January 11, 2001
First Named Inventor	Wolfgang HEIL et al.
Group Art Unit	1615
Examiner Name	L.S. Channavajjala
Attorney Docket Number	PLOVIN-2A

(use as many sheets as necessary)

Sheet	1	of	2
-------	---	----	---

[illegible][illegible]

4/14/06

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark ☐ if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:** Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box →



PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to furnish information to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

2

of

2

Complete If Known

Application Number	09/757,688
Filing Date	January 11, 2001
First Named Inventor	Wolfgang HEIL et al.
Group Art Unit	1615
Examiner Name	L.S. Channavajjala
Attorney Docket Number	PLOVIN-2A

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
<i>[Handwritten mark]</i>		K. Fotherby, et al. "Review: The new low dose oral contraceptives", Journal of Obstetrics and Gynecology, Vol. 14, (1994), pgs. 327-332.	
<i>[Handwritten mark]</i>		L. Speroff, "Review: Evaluation of a new generation of oral contraceptives", The Amer. College of Obstetricians & Gynecologists, Vol. 81, No. 6, (1993), pgs. 1034-1047.	
<i>[Handwritten mark]</i>		J. Urdinola, "Anticonceptivos orales: 30 vs. 20 µg de etinilestradio (EE), pgs. 41-49. <i>June 1993</i>	
<i>[Handwritten mark]</i>		J. Endrikat, et al., "A Twelve-Month Comparative Clinical Investigation...." Elsevier Science Inc., (1995), pgs. 229-235.	
<i>[Handwritten mark]</i>		D. Mishell, et al., "Postmenopausal hormone replacement with a combination estrogen-progestin regimen for five days per week", The Journal of Reproductive Medicine, Inc., Vol. 36, No. 5, (1991), pgs. 351-355.	
<i>[Handwritten mark]</i>		S. Sipinen, et al., "Pharmacokinetic studies on low dose estradiol 17β administered orally to postmenopausal women", Acta Obstet Gynecol Scand 59, (1980), pgs. 515-518.	
<i>[Handwritten mark]</i>		J. M. Aitken, et al., "Oestrogen replacement therapy for prevention of osteoporosis after oophorectomy", British Medical Journal, (1973), pgs. 370-375.	
<i>[Handwritten mark]</i>		C. Hassager, et al., "Estrogen/Gestagen therapy changes soft tissue body composition in postmenopausal women", Metabolism, Vol. 38, No. 7, (1989), pgs. 662-665.	
<i>[Handwritten mark]</i>		Ch. Egarter, et al., "Ovarian function during low-dose oral contraceptive use", Elsevier Science Inc., (1995).	
<i>[Handwritten mark]</i>		J. Spona, et al., "Efficacy of low-dose oral contraceptives containing levonorgestrel, gestoden and cyproterone acetate", "Gynecol, obstet, Invest., Vol. 23, (1987), pgs. 184-193.	
<i>[Handwritten mark]</i>		The Writing Group for PEPI Trail, "Effects of hormone replacement therapy on endometrial histology in postmenopausal women", Hormone Replacement Therapy, Vol. 275, No. 5, (1996) pgs. 370-375.	

Examiner
Signature

L. Channavajjala

Date
Considered

4/14/06

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.



PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0851-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1448A/PTO

(use as many sheets as necessary)

Sheet

1

of

2

Complete if Known

Application Number

09/757.688

Filing Date

January 11, 2001

First Named Inventor

Wolfgang HEIL et al.

Group Art Unit

1615

Examiner Name

L.S. Channavajjala

Attorney Docket Number

PLOVIN-2A

U.S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

[illegible]

**Examiner
Signature**

L. Chinnayyala

Date
Considered

4-14-06

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document, by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language translation is attached.

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete If Known	
				Application Number	09/757,688
				Filing Date	January 11, 2001
				First Named Inventor	Wolfgang HEIL et al.
				Group Art Unit	1615
				Examiner Name	L.S. Channavajjala
Sheet	2	of	2	Attorney Docket Number	PLOVIN-2A

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
✓		G. Levy, "Availability of spironolactone given by mouth, the Lancet, Letters to the Editor, October 6, 1962, pg. 723-724	
		Valle et al., "Farmacologia Integrada – Farmacologia Básica, Vol. I, Livraria Atheneu, Rio de Janeiro, 1998, pgs. 25-27 and 44-45 w/English translation	
		Letter dated 30 August 2005 from the Opponent	
		Translation of Opponent's letter of 30 August 2005	
		Letter of 2 November 2005 filed in response to Opponent's letter of 30 August 2005.	
✓		S. Budavari, et al., "The Merck Index", Merck & Co., Inc., Whitehouse Station, NJ (1996)	

Examiner Signature	L. Channavajjala	Date Considered	4-14-06
--------------------	------------------	-----------------	---------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

+